

S P E C I F I C A T I O N

TO ALL WHOM IT MAY CONCERN:

BE IT KNOWN that we, Anthony C. Ross and Peter A. Guagliano, have invented new and useful improvements in a

ORTHOPEDIC THERMOPOLYMER

of which the following is a specification:

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence and all referenced enclosures are being deposited by me with the United States Postal Service as Express Mail with Receipt No. EM510832727US in an envelope addressed to the Assistant Commissioner of Patents, BOX NEW PATENT APPLICATION, Washington, DC 20231 on November 21, 2001.

By: _____



ORTHOPEDIC THERMOPOLYMER

Field of the Invention

This invention relates generally to a composition that may be used to fill voids in orthopedic joints, including but not limited to the discs of the spine and joints of the extremities. More particularly, the composition may be heated and injected into
5 the body, such that the composition when cooled to body temperature becomes a flexible, yet relatively solid material. The composition may also be used to fill spaces between bone fractures or separations.

Background of the Invention

Voids, gaps, and spaces may occur in joints of the body, either through
10 natural causes, injury, or medical procedures. For example, excessive wear may cause a void in an orthopedic joint, a broken bone may result in gaps at the fracture site, and orthoscopic surgery may require removing bone or cartilage. In these and other instances, it may be useful to fill the void with a resilient, non-dispersing material. In other applications, it is desirable to deliberately form a void, for
15 example, between disks, or to increase the volume of an existing void.

Whatever the cause of the void, it is desirable to fill the void with a composition that is physiologically acceptable to the human body, and which allows the area to retain normal function and characteristics. For example, proper joint

function includes cushioning the forces on the joint and minimizing wear and abrasion to the joint. The material, when set, should therefore be resilient, pliable, and non-dispersing.

United States Patents 6,183,518, 6,206,921 and 6,264,659 disclose processes for which the present invention may be useful. Both patents describe a process for repairing invertebral disks of mammals by removing nucleus pulposus and injecting a resilient, pliable, non-dispersing material in its place. The present invention may be used with the technology disclosed in these patents to provide an improved resilient, non-dispersing material for filling the void created by removal of the nucleus pulposus and surrounding tissues.

One component of a resilient, non-dispersing material may include an isoprene powder, such as gutta percha. Gutta percha and other isoprene materials have been used, for example, in dental applications. United States Patent 6,126,446 describes a composition comprising gutta percha and other isoprene powders for filling tooth root canals. U.S. Patent No. 4,632,977 offers other filling compositions based on isoprene materials, such as gutta percha. Other patents of interest include U.S. Patents Nos. 5,047,055, disclosing a prosthetic nucleus for a vertebral disc comprised of hydrogel; 5,545,229, disclosing a replacement disc using elastomeric material in its nucleus and annulus; and 5,800,549, disclosing a method and apparatus for injecting an elastic spinal implant into a cavity in a spinal disc so as to treat disc degeneration.

Current formulations of material injectable into the spine and other parts of the body have inherent limitations. For example, some materials may be inflammatory or are otherwise incompatible with joints of many patients. Other materials may also have limited strength and durability, and may decay or degrade with time.

The present invention overcomes the disadvantage of the prior art. The composition described hereafter possesses superior mechanical properties, and is less likely to react unfavorably in the human body.

Summary of the Invention

This invention provides a composition and method for filling a void in an orthopedic joint or bone fracture site. The composition has improved mechanical and chemical properties, making it stronger, more durable, and more compatible
5 with the human body.

The preferred embodiment is a composite material, including a polymer matrix, such as gutta percha, and a dispersion phase, such as titanium particles. The components of this material cooperate synergistically, lending their individual favorable characteristics to the resulting composition. The favorable characteristics
10 of the polymer matrix, such as gutta percha, may include a relatively low weight, the ability to flow at elevated temperatures, and the ability to conform to a desired shape upon cooling to body temperature. The favorable characteristics of the titanium particles may include a low reactivity with the human body and a high strength-to-weight ratio. The composition of this invention incorporates the
15 favorable properties of both materials.

It is an object of this invention to provide a void-filling material that is injectable and moldable. Polymers such as gutta percha have the ability to flow at injection temperatures, and the ability to set in a desired shape when cooled. The polymer chosen in this invention may begin to flow above body temperature. The
20 polymer may be mixed with titanium particles and any desired fillers, heated above body temperature, then injected into the void. The composition will set upon cooling

to body temperature, thereby obtaining its resilient, non-dispersing state, and filling the void.

It is another object of this invention to provide a void-filling material that is compatible with the body. Materials that react strongly with the body are prone to degradation, and may also cause inflammation. The titanium particles discussed hereafter are inert compared with other metals and materials. Titanium is therefore less reactive in the body, and less likely to corrode or degrade into substances which might irritate surrounding tissues. Titanium's low reactivity complements its high structural strength.

10 It is a feature of this invention to provide a void-filling composition that allows
a repaired joint to retain its normal functioning and cushioning effects. The
composition provided in this invention is durable, resilient, long-lasting, and
minimizes future complications and the need for additional medical procedures.
The resiliency of a polymer, like gutta percha, when combined with the high strength
15 and toughness of titanium, give this composition its superior durability.

It is another feature of this invention that the void-filling composition is lightweight. Polymer such as gutta percha may constitute a large volume fraction of this composition, and are relatively lightweight. Titanium is among the lightest of metals suitable for this application, so the weight contribution of the titanium particles is also relatively small. The resulting composition is lightweight, and is

therefore more likely to increase mobility of joints, appendages, and other body parts on which it is used.

Yet another feature of this invention is the void-filling composition may be housed in a compressible tube. The compressible tube and its contents may be
5 heated above body temperature, such as by using hot water, an oven, or an open flame. A force may then be applied to the wall of the tube to compress the tube and discharge its contents through a nozzle. The compressible tube may thereby assist the application of the composition into the void.

Alternatively, the void-filling composition may be housed in a syringe instead
10 of a compressible tube. The syringe and its contents may be heated above body temperature, such as by using hot water, an oven, or an open flame. A plunger within the syringe may then be depressed, discharging its contents through a nozzle. The syringe, like the compressible tube, may thereby assist the application of the composition to the void.

15 It is still another feature of this invention that the titanium particles may be elongate whiskers. The elongate whiskers may further enhance the physical properties of the void-filling composition, taking advantage of various principles of composite material technology.

It is an advantage of this invention that the void-filling composition may be
20 relatively inexpensive. Polymers such as gutta percha are readily available and affordable. The growing popularity of titanium in consumer goods has led to its

increased production, deflating its classification as an exotic material, and lowering its cost. The availability and affordability of these constituent materials allows the void-filling composition to be economically viable for medical uses discussed hereafter.

5 These and further objects, features, and advantages of the present invention
will become apparent from the following detailed description, wherein reference is
made to the accompanying figures and drawings.

Brief Description of the Drawings

Figure 1 illustrates the preferred embodiment of the void-filling composition.

Titanium particles are dispersed in a polymer matrix, such as gutta percha.

Figure 2 illustrates an alternate embodiment of the void-filling composition.

5 Elongate titanium particles, or "whiskers", are dispersed in the polymer matrix.

Figure 3 illustrates a compressible tube in which the void-filling composition may be housed.

Figure 4 illustrates a syringe in which the void-filling composition may be housed.

Detailed Description of Preferred Embodiments

Figure 1 illustrates the preferred embodiment of a composition 10 for filling a void in an orthopedic joint or bone fracture site. The composition 10 includes a polymer matrix 12, such as gutta percha, and titanium particles 14. The matrix 12 has a resilient, non-dispersing, solid state at body temperature, and may be heated to a fluid state above body temperature. The matrix 12 is a thermoplastic polymer, such that when cooled to body temperature it returns to its solid state with original solid-state mechanical properties. The titanium particles 14 may consist of commercially pure titanium or a titanium alloy with comparable or greater mechanical properties. The titanium particles 14 may also constitute between 1 and 50 percent by weight of the composition 10.

The polymer matrix 12 may include a polymer known as gutta percha. Gutta-percha is a natural latex obtained from certain evergreen trees of East Asia, and has been used in products such as golf-ball coverings, surgical appliances, and adhesives. The polymer matrix 12 may comprise other polymers, such as balata and polyisoprene. Balata is a natural rubber obtained from South American trees. Balata, which is sometimes called gutta balata, has properties similar to those of gutta-percha, and its processing and uses are essentially the same. Polyisoprene may also be used as the polymer matrix. Polyisoprene, or natural rubber, is harvested from the hevea tree, and has been used to make products such as waterproof boots. Polyisoprene can be treated to give it crosslinks, which makes

it an even better elastomer. Mixtures of these materials may also be used as the polymer matrix.

The titanium particles 14 may comprise commercially pure titanium, which has excellent mechanical and chemical properties, or they may comprise a titanium alloy with even better properties. A titanium-based alloy comprising at least 50 percent by weight titanium is included within the scope of "titanium" as used herein. 5 The titanium particles 14 may be substantially spherical, with a diameter less than 50 microns. Preferably, the diameter of the titanium particles is less than 20 microns. The "size" of the titanium particles is defined as the approximate or 10 nominal diameter of the particles. A particle size may be chosen small enough that the resulting composition 10 may be a molecular mixture, with favorable properties inherent thereto, such as superior mixability with the polymer matrix 12.

The composition 10 may include one or more additives, such as: fillers, to reduce the amount of other potentially more costly materials; x-ray contrast agents, 15 to make the composition 10 visible by traditional x-ray; medicinal or pharmaceutical substances, such as antibiotics or anesthetics; waxes and resins, to increase the flowability of the composition 10; and sealers, to improve the water-resistance of the composition 10. Zinc may be added, either to the titanium alloy, or separately as additional filler particles, and may comprise up to 10 percent by weight of the 20 composition. Additives should be carefully chosen so the composition 10 retains

its beneficial properties such as strength, durability, longevity, and compatibility with the body.

The titanium particles 14 may comprise between 1 and 50 percent by weight of the composition 10. Generally, the composition 10 should include at least 5 percent by weight of titanium particles 14 to achieve benefits inherent to composite materials, and preferably the titanium particles comprise from 20 percent to 50 percent of the weight of the composition. The weight percentage of the titanium particles 14, polymer matrix 12, and any additives should be chosen to optimize the overall properties of the composition. For example, by increasing the percentage 5 of titanium particles 14, the strength of the composition 10 may likewise increase, but the weight may also increase, and the flexibility of the composition 10 may decrease. The optimum composition may be determined prior to use of the composition 10, and chosen with respect to a number of factors, including but not limited to the part of the body in which the composition 10 will be used and the size 10 of the void to be filled.

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In one embodiment, the composition 10 may be stored in a compressible tube 30, as shown in Figure 3. The composition 10 may be heated to its fluid state, then poured or otherwise transferred into the compressible tube 30 via the open port, which is subsequently plugged. The end plug 35 may then be installed into the 20 compressible tube 30, and the composition may be allowed to cool to its solid state. When needed, the composition 10 may be reheated to its liquid state from within the

compressible tube 30, such as by placing in an oven, in hot water, or over an open flame. The composition 10 may then be squeezed from the compressible tube 30, through the nozzle 34, by applying a force to the tube wall 32. The force may be applied to the tube wall 32 either by hand or through mechanical means, such as 5 by using a spring-biased roller 38. The compressible tube 30 may also facilitate the filling the void by transporting the composition 10 into the void.

In another embodiment, the composition 10 may instead be stored in a syringe 40, as shown in Figure 4. The composition 10 may be heated to its fluid state, then poured or otherwise transferred into a body 42 of the syringe 40. The 10 composition 10 may then be allowed to cool to its solid state. When needed, the composition 10 may be reheated to its liquid state from within the syringe 40, such as by placing in an oven, in hot water, or over an open flame. The composition 10 may then be expelled from the syringe 40, through the nozzle 44, by sliding the plunger 46 relative to the body 42 and toward the nozzle 44. A finger stop 48 may 15 be secured to the body 42, such that the body 42 may be held in place while the plunger 47 is depressed. For example, if the syringe 47 is hand-operated, the first and second fingers of one hand may grab the finger stop 48, while the thumb of that hand depresses the plunger 47. The syringe 40 may also facilitate filling the void by transporting the composition 10 into the void.

20 In yet another embodiment, shown in Figure 2, elongate titanium whiskers 24 may be added to a polymer matrix 22, forming a composition 20 with different

and/or improved mechanical properties. The titanium whiskers 24 may change the way the composition 10 behaves in its solid state, such as by increasing the composition's modulus of elasticity or tensile strength. The diameter of the titanium whiskers 24 may be between 1 and 50 microns, and the whisker nominal diameter defines the "size" of the titanium whisker particles. The length of the titanium whiskers 10 may be varied to further control the mechanical properties of the composition 10. For example, if titanium whiskers 24 are long enough to overlap and entangle, the strength of the composition 20 may be greater than if the titanium whiskers 24 are relatively short and distantly spaced. As with the titanium particles 14 in composition 10, the weight percentage of the titanium whiskers 24 and any additives in composition 20 may be adjusted to optimize the mechanical properties of the composition 20. The optimum length of the titanium whiskers 24 may depend on many factors, including their weight percentage, the part of the body in which the composition 20 will be used, and the size of the void to be filled.

It may be appreciated that changes to the details of the illustrated embodiments and systems disclosed are possible without departing from the spirit of the invention. While preferred and alternative embodiments of the present invention have been described and illustrated in detail, it is apparent that further modifications and adaptations of the preferred and alternative embodiments may occur to those skilled in the art. However, it is to be expressly understood that such

modifications and adaptations are within the spirit and scope of the present invention, set forth in the following claims.